

Article - Health - General

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§21–220. IN EFFECT

(a) A drug that is intended for use by human beings and is in any of the following classifications may be dispensed by a pharmacist only on a written or oral prescription from a health practitioner authorized by law to prescribe the drug:

(1) A habit-forming drug to which § 21–218(b)(1) of this subtitle applies.

(2) A drug that because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a health practitioner who is authorized by law to administer such a drug.

(3) A drug that is limited by an approved application under § 355 of the federal act or § 21–223 of this subtitle to use under the professional supervision of a health practitioner authorized by law to administer such a drug.

(b) (1) A prescription may be written or oral. However, a pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.

(2) A prescription for a controlled dangerous substance within the meaning of Title 5 of the Criminal Law Article may not be written on a preprinted prescription form that states the name, quantity, or strength of the controlled dangerous substance.

(3) When a prescription is written, a separate prescription form is required for each controlled dangerous substance. If a pharmacist is otherwise satisfied that a prescription is valid the pharmacist may fill the prescription if the pharmacist promptly writes out and files a prescription for each substance and also files the original prescription.

(4) A prescription shall be legible.

(c) A pharmacist may not refill and dispense a prescription unless the refilling is authorized by:

(1) The health practitioner's specification in the original prescription as to how many times it may be refilled; or

(2) An oral order of the health practitioner that promptly is written out and filed by the pharmacist.

(d) The dispensing of a drug without complying with the requirements of this section is the dispensing of a misbranded drug.

(e) (1) A drug that is subject to the prescription requirements of this section is misbranded if, at any time before it is dispensed, its label does not bear the statement “Caution: Federal Law Prohibits Dispensing Without Prescription”, or “Caution: State Law Prohibits Dispensing Without Prescription”.

(2) A drug to which the prescription requirements of this section do not apply is misbranded if, at any time before it is dispensed, its label bears the caution statement quoted in paragraph (1) of this subsection.

(f) (1) The prescription requirements of this section do not apply to any drug that is exempted under a rule or regulation adopted by the Secretary.

(2) The Secretary, by rule or regulation, may exempt any drug from the requirements of this section if the Secretary finds that, as to the drug, the requirements of this section are not necessary for the protection of the public health.

(3) The Secretary, by rule and regulation, may exempt from the requirements of this section any drug that is removed from the prescription requirements of the federal act by a rule or regulation adopted under that act.

§21–220. ** TAKES EFFECT JANUARY 1, 2022 PER CHAPTERS 229 AND 230 OF 2020**

(a) A drug that is intended for use by human beings and is in any of the following classifications may be dispensed by a pharmacist only on a written prescription, an electronic prescription, as defined in § 5–101 of the Criminal Law Article, or an oral prescription from a health practitioner authorized by law to prescribe the drug:

(1) A habit-forming drug to which § 21–218(b)(1) of this subtitle applies.

(2) A drug that because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a health practitioner who is authorized by law to administer such a drug.

(3) A drug that is limited by an approved application under § 355 of the federal act or § 21–223 of this subtitle to use under the professional supervision of a health practitioner authorized by law to administer such a drug.

(b) (1) Subject to paragraph (2) of this subsection and subsection (c) of this section, a prescription may be written or oral or made through an electronic prescription.

(2) A pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.

(c) (1) Except as provided in paragraph (2) of this subsection, a health practitioner authorized by law to prescribe a controlled dangerous substance within the meaning of Title 5 of the Criminal Law Article shall issue a prescription for a controlled dangerous substance using an electronic prescription, as defined in § 5–101 of the Criminal Law Article.

(2) A health practitioner may issue a written or, if authorized by State and federal law, oral prescription for a controlled dangerous substance only if:

(i) Electronic prescribing is not available due to temporary technological or electrical failure;

(ii) The prescription is to be dispensed by a pharmacy located outside the State;

(iii) The prescription is issued by a health practitioner outside the State;

(iv) The health practitioner is prescribing and dispensing the controlled dangerous substance directly to the patient;

(v) The prescription is being dispensed directly to the patient in accordance with § 12–102(c)(2)(iv) of the Health Occupations Article;

(vi) The prescription is for an individual who:

1. Resides in a nursing or assisted living facility;

2. Is receiving care through a hospice or palliative care program and the prescription is related to the care provided;

3. Is receiving care at an outpatient renal dialysis facility and the prescription is related to the care provided; or

4. Is detained or confined in a correctional facility, as defined in § 1–101 of the Correctional Services Article;

(vii) The prescription is issued by a licensed veterinarian;

(viii) The prescription includes elements that are not supported by the most recent version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;

(ix) The prescription is issued for a drug for which the federal Food and Drug Administration requires the prescription to contain certain elements that cannot be transmitted electronically;

(x) The prescription prescribes a drug under a research protocol;

(xi) The prescription is issued by a health practitioner who has received a waiver under subsection (d)(1) of this section;

(xii) The prescription is issued by a health practitioner who requested a waiver under subsection (d)(1) of this section and the Department has not issued a waiver to the practitioner or has not rejected the practitioner's request for a waiver;

(xiii) The health practitioner issuing the prescription or the drug for which the prescription is issued falls under a waiver issued by the Secretary under subsection (d)(2) of this section;

(xiv) The prescription is issued by a health practitioner who writes a low volume of prescriptions for controlled dangerous substances, as determined by the Maryland Health Care Commission; or

(xv) The prescription is issued by a health practitioner under circumstances in which, although the practitioner has the ability to issue an electronic prescription as required by paragraph (1) of this subsection, the health practitioner reasonably determines that:

1. It would be impracticable for the practitioner to prescribe the drug or device by electronic prescription in a timely manner; and

2. The delay would adversely impact the patient's medical condition.

(3) This subsection may not be construed to limit the right of a patient to designate a specific pharmacy to dispense a prescribed drug or device to the individual.

(d) (1) The Secretary shall adopt regulations, in collaboration with the Maryland Health Care Commission, to establish a process for the Department to issue a waiver from the electronic prescription requirements in subsection (c)(1) of this section.

(2) (i) The Secretary may issue a waiver that applies generally to a group of health practitioners or drugs that meet conditions specified by the Secretary.

(ii) Any waiver issued under subparagraph (i) of this paragraph for a group of health practitioners shall apply to a health practitioner in that group without requiring the health practitioner to go through the process established in regulations under paragraph (1) of this subsection.

(3) Except for a waiver issued under paragraph (2) of this subsection, the regulations adopted under paragraph (1) of this subsection shall specify that a waiver:

(i) May not exceed 1 year; and

(ii) May be granted for the following reasons:

1. Economic hardship;

2. Technological limitations that are not reasonably within the control of the health practitioner; or

3. Any other exceptional circumstances as demonstrated by the health practitioner.

(4) The Secretary may adopt regulations on:

(i) Which temporary technological or electrical failures constitute an exception to the requirement to issue an electronic prescription under subsection (c)(1) of this section; and

(ii) The circumstances under which a health practitioner is exempt from the requirement to issue an electronic prescription under subsection (c)(1) of this section because the prescription will be dispensed by a pharmacy located outside the State.

(e) The appropriate health occupations board established under the Health Occupations Article may take disciplinary action against a health practitioner who violates subsection (c) of this section.

(f) (1) A pharmacist may dispense a drug on a written or oral prescription for a controlled dangerous substance that meets the requirements of this section.

(2) A pharmacist who receives a written or oral prescription is not required to verify that the prescription is an authorized exception to the electronic prescription requirement under subsection (c)(2) of this section.

(g) (1) If a prescription for a controlled dangerous substance within the meaning of Title 5 of the Criminal Law Article is written, it may not be written on a preprinted prescription form that states the name, quantity, or strength of the controlled dangerous substance.

(2) When a prescription is written, a separate prescription form is required for each controlled dangerous substance. If a pharmacist is otherwise satisfied that a prescription is valid the pharmacist may fill the prescription if the pharmacist promptly writes out and files a prescription for each substance and also files the original prescription.

(3) A written prescription shall be legible.

(h) A pharmacist may not refill and dispense a prescription unless the refilling is authorized by:

(1) The health practitioner's specification in the original prescription as to how many times it may be refilled; or

(2) An oral order of the health practitioner that promptly is written out and filed by the pharmacist.

(i) The dispensing of a drug without complying with the requirements of this section is the dispensing of a misbranded drug.

(j) (1) A drug that is subject to the prescription requirements of this section is misbranded if, at any time before it is dispensed, its label does not bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription".

(2) A drug to which the prescription requirements of this section do not apply is misbranded if, at any time before it is dispensed, its label bears the caution statement quoted in paragraph (1) of this subsection.

(k) (1) The prescription requirements of this section do not apply to any drug that is exempted under a rule or regulation adopted by the Secretary.

(2) The Secretary, by rule or regulation, may exempt any drug from the requirements of this section if the Secretary finds that, as to the drug, the requirements of this section are not necessary for the protection of the public health.

(3) The Secretary, by rule and regulation, may exempt from the requirements of this section any drug that is removed from the prescription requirements of the federal act by a rule or regulation adopted under that act.

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